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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/856,937	08/15/2001	Loretta D. Spotila	DRE-0057	7842

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EXAMINER

JOHANNSEN, DIANA B

ART UNIT PAPER NUMBER

1634

DATE MAILED: 01/30/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/856,937

Applicant(s)

SPOTILA, LORETTA D.

Examiner

Diana B. Johannsen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 February 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 11.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

1. This application is a 371 of PCT/US99/28403, filed November 30, 1999. The International Search Report and International Preliminary Examination Report for PCT/US99/28403 have been received and considered.

Priority

2. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119(e) as follows:

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification or in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)).

(For further information regarding priority claims under 35 U.S.C. 119(e) in a national stage application, see also *MPEP* 1893.03(c)).

3. If applicant desires priority under 35 U.S.C. 119(e) based upon a previously filed copending application, specific reference to the earlier filed application must be made in the instant application. This should appear as the first sentence of the specification following the title, preferably as a separate paragraph. The status of nonprovisional parent application(s) (whether patented or abandoned) should also be included. If a parent application has become a patent, the expression "now Patent No. _____" should follow the filing date of the parent application. If a parent application has become abandoned, the expression "now abandoned" should follow the filing date of the parent application. **In the instant case**, if applicant desires priority under 35 U.S.C. 119(e), the first sentence of the specification should be amended to recite, e.g., "This

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application is the national stage of international application PCT/US99/28403, filed November 30, 1999, and claims benefit under 35 U.S.C. 119(e) of U.S. provisional application 60/110,268, filed November 30, 1998."

If the application is a utility or plant application filed on or after November 29, 2000, any claim for priority must be made during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2) and (a)(5). This time period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or 120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A priority claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed claim for priority under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) a surcharge under 37 CFR 1.17(t), and (2) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Commissioner may require additional information where there is a question whether the delay was unintentional. The petition should be directed to the Office of Petitions, Box DAC, Assistant Commissioner for Patents, Washington, DC 20231.

Information Disclosure Statement

4. The information disclosure statement (IDS) filed May 30, 2001, paper no. 11, fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and

foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. Specifically, copies of foreign patent documents AE and AF have not been provided. Accordingly, these documents have not been considered.

5. It is noted that Applicant indicated in the IDS of paper no. 11 that copies of references AE and AF were not provided (in accordance with 37 C.F.R. 1.98(d)) because these documents "were previously submitted to the U.S. Patent and Trademark Office as the PCT Receiving Office and are referenced in the International Search Report." However, the documents previously provided and cited in the ISR were not the foreign patents themselves, but rather GenCore sequence database entries corresponding to those patents (see the Form PCT/ISA/210 provided in PCT/US99/28403). Accordingly, neither the foreign patents nor translations thereof have been previously cited or provided. It is noted that the examiner has included the GenCore database citations from the Form PCT/ISA/210 of PCT/US99/28403 on the Form PTO-892 included herewith. Regarding the citation of non-English language foreign patents, Applicant is also reminded that 37 CFR 1.98(a)(3) requires applicant to provide a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of each patent listed in an IDS that is not in the English language.

Sequence Listing

6. It is noted that the Scientific and Technical Information Center made the following corrections to the computer readable form of the Sequence Listing: deleted non-ASCII "garbage" at the beginning/end of files.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 1-4 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods and kits for identifying human individuals "at risk of developing osteoporosis" comprising steps/reagents for determining the identity of the nucleotides at positions 593, 598, and 620 of exon 10 of the tumor necrosis factor alpha 2 receptor gene, does not reasonably provide enablement for methods and kits for identifying osteoporosis risk in non-human individuals, or for methods and kits for identifying osteoporosis risk in humans comprising steps/reagents for detecting a polymorphism or genotype other than the particular exon 10 genotype set forth above. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue." These

factors include, but are not limited to: (A) the breadth of the claims; (B) the nature of the invention; (C) the state of the prior art; (D) the level of one of ordinary skill; (E) the level of predictability in the art; (F) the amount of direction provided by the inventor; (G) the existence of working examples; and (H) the quantity of experimentation needed to make or use the invention based on the content of the disclosure. *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) (*MPEP* 2164.01(a)).

Claims 1-2 are drawn to methods "for identifying individuals at risk of developing osteoporosis comprising assessing the genotype of tumor necrosis factor alpha 2 receptor gene in a sample of DNA from an individual." Claim 2 is further limited to methods in which "the genotype comprising a polymorphism at nucleotides 593, 598, and 620 in exon 10 of tumor necrosis factor alpha 2 receptor gene (SEQ ID NO: 1) is indicative of the individual being at risk for developing osteoporosis." Claims 3-4 are drawn to kits "for identifying individuals at risk of developing osteoporosis comprising a means for assessing the genotype of tumor necrosis factor alpha 2 receptor gene in an individual." Claim 4 further requires that "the means detects polymorphisms at nucleotides 593, 498 and 620 in exon 10 of tumor necrosis factor alpha 2 receptor gene (SEQ ID NO:1) which are indicative of the individual being at risk for developing osteoporosis."

It is unpredictable as to whether one of skill in the art could use the invention in a manner reasonably commensurate with the instant claims. Instant claim 1 is sufficiently broad so as to encompass methods in which any genotype of the tumor necrosis factor alpha 2 receptor (TNFR2) gene is assessed in any type of "individual" in order to identify

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"individuals at risk of developing osteoporosis," while claim 3 is sufficiently broad so as to encompass kits "for identifying individuals at risk of developing osteoporosis" comprising any "means for assessing the genotype of" TNFR2 in any "individual." The term "genotype" as employed in the specification is not limited to, e.g., a particular combination of polymorphic sites shown to have an association with disease, and encompasses any type of genotype, including those shown to have no association with disease. For example, the specification refers to various intron 4 "genotypes" of TNFR2, and teaches that none of these genotypes are significantly associated with osteoporosis (see pages 5-6). Accordingly, claims 1 and 3 encompass steps/reagents (respectively) for assessing any type of TNFR2 gene genotype to accomplish "identifying individuals at risk of developing osteoporosis." The specification does provide evidence that a particular allele of exon 10 of the TNFR2 gene, allele 1, is associated with low bone density and risk of osteoporosis in humans (see entire specification, especially pages 7-9). The specification teaches that instant SEQ ID NO: 1 corresponds to exon 10 of TNFR2, and that allele 1 is a combination of particular nucleotides at three polymorphic sites of exon 10/SEQ ID NO: 1, specifically, an A at nucleotide 593, a G at nucleotide 598, and a T at nucleotide 620 (see page 7 of the specification). However, as indicated above, the specification also teaches that the intron 4 genotype of TNFR2 is not associated with osteoporosis (pages 5-6). Further, the specification does not provide evidence of any other TNFR2 genotypes that have a disease association. Lacking guidance from the specification, one of skill in the art may look to the teachings of the art for additional guidance and enablement of a claimed

invention. In the instant case, the prior art as exemplified by Beltinger et al (Genomics 35(1):94-100 [1996]) discloses the intron 4 polymorphism described in the specification (see entire reference, especially p. 97, right column), and the prior art as exemplified by Kaufman et al (Human Molecular Genetics 2(6):824 [1993]) discloses a single strand conformational polymorphism of TNFR2 exon 10 that corresponds in location to the exon 10 polymorphisms of the specification (see entire reference). However, the prior art does not indicate that polymorphism(s) of either of these regions are associated with osteoporosis, and the prior art is silent with respect to any other polymorphisms or genotypes of TNFR2 that are associated with osteoporosis. Further, it is well known to those of skill in the art that many genetic mutations/polymorphisms found in genes have no effect on protein structure and/or activity and bear no relationship to disease predisposition; absent evidence of an association between a particular genotype or polymorphism and a particular disease or condition, it is completely unpredictable as to whether any such association exists. In the instant case, in view of the teachings of the specification and of the art, and in view of the high skill level of one of skill in the relevant art, a skilled artisan could employ a variety of different methods well known in the art to detect allele 1 of TNFR2 exon 10 as an indicator of risk for developing osteoporosis in humans. However, while one of skill in the art could conduct further research and experimentation to determine whether any other polymorphisms or genotypes of TNFR2 are associated with osteoporosis, it is unknown as to whether any other such genotypes or polymorphisms of TNFR2 even exist. Thus, it is unpredictable as to whether any quantity of experimentation would be sufficient to identify other

disease-associated genotypes of TNFR2. Additionally, it is noted that neither the specification nor the art provide any teachings or evidence in support of an association between any TNFR2 genotype and osteoporosis risk in any non-human "individuals." Given this complete absence of guidance, it is further unpredictable as to whether applicant's methods/reagents could be employed successfully in non-human individuals. Accordingly, while the teachings of the specification and of the art would enable one of skill in the art to successfully employ methods and kits for identifying human individuals "at risk of developing osteoporosis" comprising steps/reagents for determining the identity of the nucleotides at positions 593, 598, and 620 of exon 10 of the tumor necrosis factor alpha 2 receptor gene, it would require undue experimentation to use applicant's invention in a manner reasonably commensurate with the instant claims.

With further regard to claim 3, it is noted that the claim is drawn to kits "for identifying individuals at risk of developing osteoporosis." As discussed above, the combined teachings of the specification and the art reveal only a single particular combination of polymorphisms in exon 10 that are associated with osteoporosis risk. In contrast, claim 3 is sufficiently broad so as to encompass a kit comprising any "means for assessing" any genotype of TNFR2. It is well known to those of skill in the art that a vast number of reagents may be employed in genotyping, and further, the claim as written encompasses kits comprising reagents for detecting, e.g., the intron 4 polymorphism shown in the specification to have no association with osteoporosis, and, e.g., probes/primers specific for detecting any other TNFR2 genotype. As discussed above, it is unknown as to whether such reagents would prove to be useful in

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"identifying individuals at risk of developing osteoporosis;" accordingly, it would require undue experimentation to use the invention in a manner reasonably commensurate with the claim.

With further regard to claims 2 and 4, it is noted that while the claims are limited to particular combinations of polymorphisms, the claims encompass steps/reagents that detect this combination as indicative of osteoporosis risk in non-human individuals. As discussed above, it would require undue experimentation to employ such steps/reagents in determining osteoporosis risk in an individual other than a human, as the specification and the art are silent with respect to any such association.

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 1, 2, and 4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 2 are indefinite because it is unclear as to whether the claims are intended to be drawn to methods "for identifying individuals at risk of developing osteoporosis," as recited in the claim preamble, or to methods of "assessing the genotype of tumor necrosis factor alpha 2 receptor gene in a sample of DNA from an individual," as recited in the final process step of the claimed method. The claims should be amended so as to clarify how the step of "assessing the genotype" relates to/results in "identifying individuals at risk of developing osteoporosis."

Claim 2 is indefinite over the recitation of the limitation "the genotype comprising a polymorphism at nucleotides 593, 598, and 620 in exon 10 of tumor necrosis factor alpha 2 receptor gene (SEQ ID NO:1)." While the recitation of the general and well known terminology "the genotype" in the phrase "assessing the genotype" in claim 1 (as well as in claim 3) is clear and definite, there is insufficient antecedent basis in the claims for the limitation "the genotype comprising a polymorphism at nucleotides 593, 598, and 620 in exon 10 of tumor necrosis factor alpha 2 receptor gene (SEQ ID NO:1)," as this particular genotype has not been previously recited. This rejection could be overcome by amending the claim to recite, e.g., "wherein detection of a genotype comprising _____ is indicative of _____."

Claim 2 is indefinite over the recitation "genotype comprising a polymorphism at nucleotides 593, 598, and 620 in exon 10 of tumor necrosis factor alpha 2 receptor gene (SEQ ID NO:1) is indicative of the individual being at risk for developing osteoporosis." It is unclear as to whether this language is intended to indicate that one is to detect the particular combination of polymorphisms present in SEQ ID NO: 1 as indicative of risk, or whether one is to detect nucleotides that are polymorphic/different as compared to SEQ ID NO: 1 as indicative of risk. It is noted that the specification discloses that the combination of polymorphisms set forth in SEQ ID NO: 1 correspond to the sequence of allele 1, which is disclosed as being associated with risk (see SEQ ID NO: 1 and Table 3). Further, it is unclear as to how the recitation of "(SEQ ID NO:1)" in the claim is intended to limit the claim. For example, is this recitation intended to require detection of this entire sequence as part of the claimed method, is it intended

only to clarify the location of the recited polymorphic sites within exon 10 of the TNFR2 gene, etc.? Clarification is required such that one of skill in the art would be apprised as to what genotype of exon 10 of TNFR2 is "indicative of the individual being at risk for developing osteoporosis," and as to what must actually be assessed/determined to meet the limitations of the claim.

Claim 4 is indefinite over the recitation of the phrase "polymorphisms at nucleotides 593, 598 and 620 in exon 10 of tumor necrosis factor alpha 2 receptor gene (SEQ ID NO: 1) which are indicative of the individual being at risk for developing osteoporosis." It is unclear as to whether this language is intended to require "means" that detect the particular combination of polymorphisms present in SEQ ID NO: 1, or means that detect nucleotides that are polymorphic/different as compared to SEQ ID NO: 1. It is noted that the specification discloses that the combination of polymorphisms set forth in SEQ ID NO: 1 correspond to the sequence of allele 1, which is disclosed as being associated with risk (see SEQ ID NO: 1 and Table 3). Further, it is unclear as to how the recitation of "(SEQ ID NO:1)" in the claim is intended to limit the claim. For example, is this recitation intended to require means that detect this entire sequence, is it intended only to clarify the location of the recited polymorphic sites within exon 10 of the TNFR2 gene, etc.? Clarification is required such that one of skill in the art would be clearly apprised as to the types of reagents that are encompassed by the claim.

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. Claims 3-4 are rejected under 35 U.S.C. 102(b) as being anticipated by the New England Biolabs 1992 Catalog (New England Biolabs, Inc., 1992, page 101).

The claims are drawn to kits comprising “a means for assessing the genotype of tumor necrosis factor alpha 2 receptor gene in an individual.” Claim 4 further requires that “the means detects polymorphisms at nucleotides 593, 598 and 620 in exon 10 of tumor necrosis factor alpha 2 receptor gene (SEQ ID NO:1).”

The instant specification discloses that a variety of reagents and methods may be employed in assessing TNFR2 genotype (see specification page 10), and exemplifies determination of the particular polymorphisms of instant claim 4 by DNA sequencing (see Example 4). The New England Biolabs 1992 Catalog teaches a kit comprising reagents for DNA sequencing (see entire reference). The New England Biolabs catalog therefore teaches a kit comprising reagents meeting the requirements of the instant claims, that is, reagents that constitute a “means for assessing the genotype” of the TNFR2 gene, including the particular genotype of claim 4.

It is noted that the recitation of the intended use “for identifying individuals at risk of developing osteoporosis” in the preamble of claim 3 does ^{not} result in a structural difference between the claimed invention and the kit taught by New England Biolabs, and further that the kit of New England Biolabs is capable of performing the intended use. Accordingly, the New England Biolabs 1992 Catalog anticipates the claimed

invention. (See *MPEP* 2111.02 for a further discussion of the weight given to preamble statements reciting purpose or intended use of a claimed product).

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:


(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

14. Claims 3-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kaufman et al (Human Molecular Genetics 2(6):824 [1993]) in view of Ahern (The Scientist 9(15):20 [7/1995]).

The claims are drawn to kits comprising "a means for assessing the genotype of tumor necrosis factor alpha 2 receptor gene in an individual." Claim 4 further requires that "the means detects polymorphisms at nucleotides 593, 598 and 620 in exon 10 of tumor necrosis factor alpha 2 receptor gene (SEQ ID NO:1)." The specification discloses at page 10 that a preferred kit comprising a means for assessing TNFR2 genotype is a kit that "comprises primers such as exemplified by SEQ ID NO: 4 and SEQ ID NO: 5 described in Example 3." Applicant's Example 3 describes the genotyping of the exon 10 polymorphism of instant claim 4 (see page 12 of the specification).

Kaufman et al disclose a method for identifying a single strand conformational polymorphism (SSCP) in the TNFR2 gene (see entire reference). Kaufman et al's method employs PCR reagents, including primers TNFR2-7 and TNFR2-8, which

correspond to instant SEQ ID Nos 4 and 5, respectively (see page 12 of the specification). Kaufman et al do not disclose the packaging of the reagents employed in their method into a kit. Ahern teaches that premade reagents provided in kit form are convenient and save researchers time and money (see pages 3/5-4/5). In view of the teachings of Ahern, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have modified the invention of Kaufman et al so as to have packaged the primers and other reagents taught by Kaufman et al into a kit. An ordinary artisan would have been motivated to have made such a modification in order to have provided the reagents needed to perform Kaufman et al's SSCP method to practitioners in a convenient format for the advantages of convenience, efficiency and cost-effectiveness.

 It is noted that the recitation of the intended use "for identifying individuals at risk of developing osteoporosis" in the preamble of claim 3 does ^{not} result in a structural difference between the claimed invention and the kit suggested by Kaufman et al in view of Ahern, and further that the kit suggested by Kaufman et al in view of Ahern is capable of performing the intended use. (See *MPEP* 2111.02 for a further discussion of the weight given to preamble statements reciting purpose or intended use of a claimed product).

Conclusion

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Diana B. Johannsen whose telephone number is

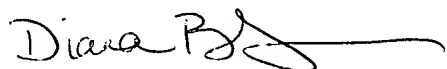
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703/305-0761. The examiner can normally be reached on Monday-Friday, 7:30 am-4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached at 703/308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are 703/872-9306 for regular communications and 703/872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703/308-0196.

A handwritten signature in cursive script, appearing to read "Diana B. Johannsen", followed by a long horizontal flourish.

Diana B. Johannsen
January 27, 2003